

## ESTIMATED ANNUALIZED BURDEN HOURS

Form	A. Estimates annual burden hours			
	Number of respondents	Frequency of response	Average time per response (in hours)	Annual burden hour
NIMH Data Repositories Data Submission Request Form .....	40	1	95/60	63
NIMH Data Repositories Data Access and Use Certification Form .....	100	1	95/60	158

Dated: December 15, 2014.

**Keisha Shropshire,**

*NIMH Project Clearance Officer, NIMH, NIH.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; 30-Day Comment Request; The NIH/NCATS GRDR<sup>SM</sup> Program: Global Rare Diseases Patient Registry Data Repository (GRDR)

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on July 30, 2014, page 44185 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or

implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

**DATES:** *Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

**ADDRESSES:** Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA\_submission@omb.eop.gov* or by fax to 202-395-6974, Attention: NIH Desk Officer.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project contact: Dr. Yaffa Rubinstein, Director of Patient Resources for Clinical and Translational Research at the Office of Rare Diseases Research (ORDR), NCATS, NIH, Suite 1004, 6701 Democracy Boulevard, Bethesda, MD 20892-4874, or call non-toll-free number (301) 402-4338 or Email your request, including your address to: *yaffa.rubinstein@nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

**SUPPLEMENTARY INFORMATION:** Proposed Collection: NIH/NCATS GRDR<sup>SM</sup> Program: Global Rare Diseases Patient Registry Data (GRDR), The National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH).

**Need and Use of Information Collection:** The NIH created the GRDR program <https://grdr.ncats.nih.gov> an informatics system and central data repository, housed at the NCATS/NIH Center to support and accelerate research in the cause, diagnosis, and treatment of rare diseases. The GRDR program collects a wide range of data types, including phenotypic and clinical information, as well as medical images, derived from individuals who participate in rare disease patient registries, regardless of the source of funding. The GRDR program provides the infrastructure to store, search across, retrieve, and analyze these varied types of data. This valuable information will help NIH understand and evaluate the use of repositories/datasets in the research community. The GRDR program will support: (1) Mapping data to standards; (2) increased visibility for participating registries; (3) opportunity for cross-disease research; (4) better and faster rare disease clinical research.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 133.

## ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Request for Open .....	Individuals .....	2000	1	1/60	33
Request for Controlled .....	Individuals .....	1000	1	5/60	83
Request to Submit .....	Individuals .....	100	1	10/60	17

Dated: December 9, 2014.

**Pamela McInnes,**

*Deputy Director, NCATS, NIH.*

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